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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,103	09/12/2003	Parminder Singh	2335-0008.22	6566

79975 7590 03/07/2011

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
03/07/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/661,103	SINGH ET AL.	
	Examiner	Art Unit	
	Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 August 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38 and 40-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-38 and 40-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/30/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' amendment and request for RCE filed 08/27/2010 and IDS filed 08/30/2010.

Claims 1-38 and 40-60 are pending and included in the prosecution.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/27/2010 has been entered.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims

are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-38 and 40-60 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 56, 57, 59, 61, and 85-107 of copending Application No. 10/137,664 in view of Tapolsky et al. (WO 99/55312, currently provided). The present claims and the claims of the copending application both recite composition comprising water-swellable polymer, a blend of and

hydrophilic polymer and complementary oligomer, and active agent. The difference between the present claims and the copending claims is that the copending claims do not recite erodible backing layer. Tapolsky teaches device to provide treatment to a localized site in the oral cavity comprising erodible backing. The residence time of the device can be adjusted by adjusting the polymer components of the backing depending on the desired timing of the delivery of the chosen pharmaceutical (abstract; page 9, lines 12-31). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide composition comprising water swellable polymer, blend of hydrophilic polymer and complementary polymer, and active agent as claimed by the copending application, and further add erodible backing taught by Tapolsky. One would have been motivated to do so because Tapolsky teaches that the residence time of the device in the oral cavity can be adjusted by adjusting erodability of the backing depending on the desired timing of delivery of the chosen pharmaceutical. One would reasonably expect formulating device comprising erodible backing and composition comprising water swellable polymer, blend of hydrophilic polymer and complementary polymer and active agent as instantly claimed, wherein the erodability of the backing layer can be adjusted depending on the desired timing of the delivery of the chosen pharmaceutical.

This is a provisional obviousness-type double patenting rejection.

4. Claims 1-38 and 40-60 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 7-9,14-19,

21, 23-34, 36-40, 46, 53, 56-61 and 63-71 of copending Application No. 10/359,548 in view of Tapolsky et al. (WO 99/55312). The present claims and the claims of the copending application both recite composition comprising water-swellable polymer, a blend of and hydrophilic polymer and complementary oligomer, and active agent. The difference between the present claims and the copending claims is that the copending claims do not recite erodible backing layer. Tapolsky teaches device to provide treatment to a localized site in the oral cavity comprising erodible backing. The residence time of the device can be adjusted by adjusting the polymer components of the backing depending on the desired timing of the delivery of the chosen pharmaceutical (abstract; page 9, lines 12-31). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide composition comprising water swellable polymer, blend of hydrophilic polymer and complementary polymer, and active agent as claimed by the copending application, and further add erodible backing taught by Tapolsky. One would have been motivated to do so because Tapolsky teaches that the residence time of the device in the oral cavity can be adjusted by adjusting erodability of the backing depending on the desired timing of delivery of the chosen pharmaceutical. One would reasonably expect formulating device comprising erodible backing and composition comprising water swellable polymer, blend of hydrophilic polymer and complementary polymer and active agent as instantly claimed, wherein the erodability of the backing layer can be adjusted depending on the desired timing of the delivery of the chosen pharmaceutical.

This is a provisional obviousness-type double patenting rejection.

5. Claims 1-38 and 40-60 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-48 of copending Application No. 10/848,538 in view of Tapolsky et al. (WO 99/55312). The present claims and the claims of the copending application both recite composition comprising water-swellable polymer, a blend of and hydrophilic polymer and complementary oligomer, and active agent. The difference between the present claims and the copending claims is that the copending claims do not recite erodible backing layer. Tapolsky teaches device to provide treatment to a localized site in the oral cavity comprising erodible backing. The residence time of the device can be adjusted by adjusting the polymer components of the backing depending on the desired timing of the delivery of the chosen pharmaceutical (abstract; page 9, lines 12-31). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide composition comprising water swellable polymer, blend of hydrophilic polymer and complementary polymer, and active agent as claimed by the copending application, and further add erodible backing taught by Tapolsky. One would have been motivated to do so because Tapolsky teaches that the residence time of the device in the oral cavity can be adjusted by adjusting erodability of the backing depending on the desired timing of delivery of the chosen pharmaceutical. One would reasonably expect formulating device comprising erodible backing and composition comprising water swellable polymer, blend of hydrophilic polymer and complementary polymer and active agent as instantly claimed, wherein the erodability of the backing

layer can be adjusted depending on the desired timing of the delivery of the chosen pharmaceutical.

This is a provisional obviousness-type double patenting rejection.

6. Claims 1-38 and 40-60 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-65 of copending Application No. 12/491,088 in view of Tapolsky et al. (WO 99/55312). The present claims and the claims of the copending application both recite composition comprising water-swellable polymer, a blend of and hydrophilic polymer and complementary oligomer, and active agent. The difference between the present claims and the copending claims is that the copending claims do not recite erodible backing layer. Tapolsky teaches device to provide treatment to a localized site in the oral cavity comprising erodible backing. The residence time of the device can be adjusted by adjusting the polymer components of the backing depending on the desired timing of the delivery of the chosen pharmaceutical (abstract; page 9, lines 12-31). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide composition comprising water swellable polymer, blend of hydrophilic polymer and complementary polymer, and active agent as claimed by the copending application, and further add erodible backing taught by Tapolsky. One would have been motivated to do so because Tapolsky teaches that the residence time of the device in the oral cavity can be adjusted by adjusting erodability of the backing depending on the desired timing of delivery of the chosen pharmaceutical. One would

reasonably expect formulating device comprising erodible backing and composition comprising water swellable polymer, blend of hydrophilic polymer and complementary polymer and active agent as instantly claimed, wherein the erodability of the backing layer can be adjusted depending on the desired timing of the delivery of the chosen pharmaceutical.

This is a provisional obviousness-type double patenting rejection.

Copending Applications

7. Applicants must bring to the attention of the examiner, or other Office official involved with the examination of a particular application, information within their knowledge as to other copending United States applications, which are "material to patentability" of the application in question. MPEP 2001.06(b). See Dayco Products Inc. v. Total Containment Inc., 66 USPQ2d 1801 (CA FC 2003).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1-38, 40-41, 46-49 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tapolsky et al. (WO 99/55312, currently provided) in view of Roreger et al. (US 5,456,745, IDS filed 12/19/2003).

Applicant Claims

Applicants' claim 1 is directed to composition comprising:

(a) a hydrogel comprising:

(i) a water-swellable, water-insoluble polymer;

(ii) a blend of a hydrophilic polymer with a complementary oligomer capable of hydrogen or electrostatic bonding to the hydrophilic polymer; and

(iii) an active agent; and

(b) a backing member, where the backing member is comprised of a polymer composition that erodes in a moist environment at a slower rate than the hydrogel.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

Tapolsky teaches erodible pharmaceutical device for application to the mucosal surface, the device comprising one adhesive layer and non-adhesive backing layer. Upon application to the mucous surface the device adheres and provides localized delivery to the treatment site and surrounding tissues. The kinetics of erodability are easily adjusted by varying the layer numbers or components (abstract; page 20, lines 30-31). Both adhesive and backing layers are water soluble, i.e. erodible (page 5, lines 11-13). The adhesive layer comprises from 0.005 to about 20% active agent, polymer selected from cellulose derivatives, which is water swellable polymer, combined with polymer selected from polyacrylic acid or polyvinyl pyrrolidone, which is water soluble hydrophilic polymer (page 5, lines 20-27; page 10, line 14 till page 11 line 12; page 17, lines 25-28; examples 11 and 12). Table 1, page 27 teaches up to 10% PVP, and 0.05-20% water swellable cellulose derivatives, and 0.5-10% polyacrylic acid. The adhesive

layer further comprises polyethylene glycol, dihydroxy-polyethylene glycol and butylene glycol up to 20%, all claimed as oligomer (page 13, lines 10-14; page 14, lines 21-24; page 20, lines 5-11). Oligomers taught by the reference are expected to have the capability of hydrogen and electrostatic bonding to the hydrophilic polymer since compounds and their properties are inseparable. The backing layer comprises hydroxyethyl cellulose, hydroxypropyl cellulose or hydroxypropylmethyl cellulose, polysaccharide, polyamino acid and their derivatives, and cellulose acetate (page 5, line 28 till page 6, line 13; page 12, lines 5-25; page 13, line 24). Both layers may contain coloring agent, flavoring agent or preservatives (page 17, lines 28-30). Example 37 teaches gel composition. The device may be solid (page 8, line 10). The residence time of the device can be adjusted by adjusting the polymer components of the backing depending on the desired timing of the delivery of the chosen pharmaceutical and carrier (page 9, lines 12-31). The layers of device absorbs water (page 9, lines 26-29), i.e. capable to from hydrogel. The residence time is modulated between about few seconds to about few days, and preferably between 30 minutes and 24 hours, and more preferably between about 1 hour to about 8 hours (page 10, lines 1-6). The adhesive layer containing the active agent will erode first and the backing layer has slower erosion time as it provides protection to the drug containing layer (page 10, lines 7-13). The device may have additional layer to ensure unidirectional release of the active agent (page 19, lines 3-6).

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

Although Tapolsky teaches combination of polymers including water swellable polymer and hydrophilic polymer, and suggests oligomer, however the reference does not exemplify the oligomer in the composition. Tapolsky does not teach translucent composition as instantly claimed by claim 16.

Roreger teaches hydrophilic flexible gel film that exhibits mechanical stability in swollen condition and has a high water absorption capacity, handling stability and optimum skin and mucous membrane tolerance (col.2, lines 11-17; cool.7, lines 25-28). The high water absorption capacity reads on hydrogel. The film is transparent (col.12, lines 51-67). The gel film is suitable for delivery of pharmaceuticals and cosmetics to the mucous membrane of the buccal cavity including fluorides (abstract; co1.1, lines 15-23; col.10, lines 61-65). The film can be used as a single layer. If applicable to the mucous membrane, the film may have a backing layer that can be resorbable (col.8, line 35; col.10, lines 54-60). Example 12 on column 14 of Roreger teaches gel film comprises the same water swellable water insoluble polymer disclosed by applicants in the present specification page 15 including Eudragit S 100 in amount of 7.5%, Eudragit E 100 in an amount of 7.5%, hydrophilic polymer polyvinylpyrrolidone (PVP) and oligomer propylene glycol. Roreger also teaches utilization of Eudragit L and Eudragit LS polymers (col.2, lines 50-67), and cellulose polymer containing cellulose acetate (col.2, lines 36-42). The gel film comprises back layer (col.6, lines 16-18).

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

It would have been obvious to one having ordinary skill in the art at the time of the invention to provide device for drug delivery to the mucosa and surrounding tissues comprises an erodible backing layer and layer comprising active agent in a polymer combination as taught by Tapolsky, and replace the polymer composition containing the active agent with the translucent composition taught by Roreger comprising water swellable polymer such as Eudragit E 100 or Eudragit S 100 , PVP and polyethylene glycol. One would have been motivated to do so because Roreger teaches that combination of water swellable polymer, PVP and oligomer provides translucent flexible gel film that exhibits mechanical stability in swollen condition and has a high water absorption capacity, handling stability and optimum mucous membrane tolerance and capable of delivering of active agents to the buccal cavity including fluoride. One would reasonably expect formulating translucent gel/hydrogel composition comprises PVP, PEG and water swellable polymer wherein the composition suitable to deliver active agent including fluoride to the buccal cavity, and further the composition is stable in swollen condition and has a high water absorption capacity, handling stability and optimum mucous membrane tolerance.

Regarding the capability of the oligomer of hydrogen and electrostatic bonding to the hydrophilic polymer as claimed by claim 1, this is an intrinsic property since compounds and their properties are inseparable.

Regarding the specific materials of the backing as claimed by claims 9, 12, 13 and 15, applicants failed to show unexpected results obtained from the use of

polyacrylate, starch or alginate over the cellulose derivatives or polyamino acids taught by Tapolsky.

Regarding the claimed amounts of the polymers and active agent as claimed by claims 18-26, Tapolsky and Roreger teach amounts overlapping with the claimed amounts. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. **See MPEP 2144.05 [R-5].**

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

12. Claims 42-45, 50-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Tapolsky in view of Roreger as applied to claims 1-38, 40-41, 46-49 and 60, and further in view of Ye et al. (WO 01/01958, currently provided).

Applicant Claims

Applicant s' claims 42-45 recite the active agent of claim 1 is a whitening agent.

Claim 50 is directed to a method for whitening teeth comprising:

applying to teeth in need of whitening a composition comprising:

(a) a hydrogel comprising: (i) a water-swellable, water-insoluble polymer; (ii) a blend of a hydrophilic polymer with a complementary oligomer capable of hydrogen or electrostatic bonding to the hydrophilic polymer; and (iii) an active agent; and

(b) a backing member, where the backing member is comprised of a polymer composition that erodes in the oral cavity at a slower rate than the hydrogel.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

The combined teachings of Tapolsky and Roreger are previously discussed in this office action. The combined teachings of the references teaches composition comprising: (a) a hydrogel comprising: (i) a water-swellable, water-insoluble polymer; (ii) a blend of a hydrophilic polymer with a complementary oligomer capable of hydrogen or electrostatic bonding to the hydrophilic polymer; and (iii) an active agent; and (b) erodible backing member.

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

While the combination of the references teaches active agent in the device for delivery to the buccal cavity including fluoride, however, the references do not explicitly teach whitening agent as claimed by claims 42-45 or the method of whiting teeth as claimed by claim 50-59.

Ye teaches delivery device for delivering oral care agent to the oral cavity comprising removable backing layer and oral care composition to contact the oral surface. Ye teaches the removable backing layer has sufficient flexibility so as to be readily comfortable to the oral surface when placed therein. Ye teaches removable

backing intended to include removal as a result of in-situ dissolution in the oral cavity without the need of manual peeling which is very convenient to the consumer and provides added safety during overnight use (abstract; page 7, lines 10-11, 31-35). Oral care composition comprises teeth whiting agents including peroxides, metal chlorites, perborates, percarbonates, peroxyacids and combination thereof. Peroxides include hydrogen peroxide, urea peroxide, calcium peroxide, and carbamide peroxide. Metal chlorites include sodium chlorite, calcium chlorite, magnesium chlorite, barium chlorite, potassium chlorite and lithium chlorite (page 14, lines 23-33). Oral care composition comprises fluorides (page 16, lines 3-30). The reference teaches method of using the device comprising applying the device to the desired surface to obtain the desired effect such as whitening the teeth by applying the device to the desired area of the teeth surfaces (page 28, lines 12-28).

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide device comprising erodible backing and gel/hydrogel composition comprises PVP, PEG and water swellable polymer wherein the composition suitable to deliver active agent including fluoride to the buccal cavity as taught by the combination of Tapolsky and Roreger, and replace the fluoride with teeth whitening agent and use the device for teeth whitening as taught by Ye. One would have been motivated to do so because Ye teaches that teeth whitening can be

performed by using device having erodible backing applied to the surface of the teeth because such a device is very convenient to the consumer and provides added safety during overnight use. One would reasonably expect formulating device comprising erodible backing and composition comprising gel/hydrogel comprises PVP, PEG and water swellable polymer and teeth whitening agent wherein the device can be applied to the surface of the tooth to achieve whitening while being comfortable, convenient and safe to the consumer.

Regarding application of the composition and the backing in subsequent steps as claimed by claim 53, applicants failed to provide unexpected results obtained from subsequent application over the single step application taught by the prior art.

Regarding the predetermined period of time to achieve teeth whitening as claimed by claims 56-58, those of ordinary skill in the art would have been readily optimized the period of administration based on the dosages of whitening agent used. Doses and administration regimens can be determined by good medical practice and the clinical condition of the individual patient. Determination of the appropriate dosage for treatment involving the above mentioned formulation would have been routinely made by those of ordinary skill in the art and is within the ability of tasks routinely performed by them without undue experimentation.

One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01(a)

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

13. Claims 50-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ye (WO 01/01958) in view of Tapolsky (WO 99/55312), both references are currently provided.

Applicant Claims

Claim 50 is directed to a method for whitening teeth comprising:

applying to teeth in need of whitening a composition comprising:

(a) a hydrogel comprising: (i) a water-swellable, water-insoluble polymer; (ii) a blend of a hydrophilic polymer with a complementary oligomer capable of hydrogen or electrostatic bonding to the hydrophilic polymer; and (iii) an active agent; and

(b) a backing member, where the backing member is comprised of a polymer composition that erodes in the oral cavity at a slower rate than the hydrogel.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

Ye teaches delivery device for delivering oral care agent to the oral cavity comprising removable backing layer and oral care composition to contact the oral surface. Ye teaches the removable backing layer has sufficient flexibility so as to be

readily comfortable to the oral surface when placed therein. Ye teaches removable backing intended to include removal as a result of in-situ dissolution in the oral cavity without the need of manual peeling which is very convenient to the consumer and provides added safety during overnight use (abstract; page 7, lines 10-11, 31-35). Oral care composition comprises teeth whiting agents including peroxides, metal chlorites, perborates, percarbonates, peroxyacids and combination thereof. Peroxides include hydrogen peroxide, urea peroxide, calcium peroxide, and carbamide peroxide. Metal chlorites include sodium chlorite, calcium chlorite, magnesium chlorite, barium chlorite, potassium chlorite and lithium chlorite (page 14, lines 23-33). Oral care composition comprises fluorides (page 16, lines 3-30). The reference teaches method of using the device comprising applying the device to the desired surface to obtain the desired effect such as whitening the teeth by applying the device to the desired area of the teeth surfaces (page 28, lines 12-28).

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Ye however, does not teach the composition containing the teeth whitening agent comprising water-swellable, water-insoluble polymer; a blend of a hydrophilic polymer with a complementary oligomer capable of hydrogen or electrostatic bonding to the hydrophilic polymer as instantly claimed by claim 50.

Tapolsky teaches erodible pharmaceutical device for application to the buccal cavity, the device comprising one adhesive layer and non-adhesive backing layer. Upon

application to the mucous surface the device adheres and provides localized delivery to the treatment site and surrounding tissues. The kinetics of erodability of the backing layer are easily adjusted by varying the layer numbers or components (abstract; page 20, lines 30-31). Both adhesive and backing layers are water soluble, i.e. erodible (page 5, lines 11-13). The adhesive layer comprises active agent, one polymer selected from cellulose derivatives, which is water swellable polymer, combined with polymer selected from polyacrylic acid or polyvinyl pyrrolidone, which is water soluble polymer (page 5, lines 20-27; page 10, line 14 till page 11 line 12; page 17, lines 25-28; examples 11 and 12). The adhesive layer further comprises polyethylene glycol, dihydroxy-polyethylene glycol and butylene glycol up to 20%, which are the claimed oligomers (page 13, lines 10-14; page 14, lines 21-24; page 20, lines 5-11). Oligomer are expected to have the capability of hydrogen and electrostatic bonding to the hydrophilic polymer since compounds and their properties are inseparable. Example 37 teaches gel composition. The residence time of the device can be adjusted by adjusting the polymer components of the backing depending on the desired timing of the delivery of the chosen pharmaceutical and carrier (page 9, lines 12-31). The device absorbs water (page 9, lines 26-29), i.e. capable to from hydrogel. The residence time is modulated between about few seconds to about few days, and preferably between 30 minutes and 24 hours, and more preferably between about 1 hour to about 8 hours (page 10, lines 1-6). The adhesive layer containing the active agent will erode first and the backing layer will have slower erosion time as it provides protection to the drug containing layer (page 10,

lines 7-13). The device may have additional layer to ensure unidirectional release of the active agent (page 19, lines 3-6).

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to white teeth using a device comprising an erodible backing and whitening-agent-containing layer as taught by Ye, and replace whitening-agent-containing layer with the composition taught by Tapolsky comprising water swellable polymer, hydrophilic polymer and oligomer to deliver the teeth whitening agent. One would have been motivated to do so because Tapolsky teaches that such a composition is completely erodible and the kinetics of erodability of the composition are easily adjusted by varying the components and can be modulated between about few seconds to about few days. One would reasonably expect whitening the teeth using a device comprising an erodible backing and teeth-whitening-containing layer comprising water swellable polymer, hydrophilic polymer and oligomer wherein the device is completely erodible and its erodability is easily modulated between about few seconds to about few days to achieve the desired teeth whitening effect in the desired time.

Regarding the capability of oligomer of hydrogen and electrostatic bonding to the hydrophilic polymer as claimed by claim 50, this is an intrinsic property since compounds and their properties are inseparable.

Regarding application of the composition and the backing in subsequent steps as claimed by claim 53, applicants failed to provide unexpected results obtained from subsequent application over the single step application taught by the prior art.

Regarding the predetermined period of time to achieve teeth whitening as claimed by claims 56-58, those of ordinary skill in the art would have been readily optimized the period of administration based on the dosages of whitening agent used. Doses and administration regimens can be determined by good medical practice and the clinical condition of the individual patient. Determination of the appropriate dosage for treatment involving the above mentioned formulation would have been routinely made by those of ordinary skill in the art and is within the ability of tasks routinely performed by them without undue experimentation.

One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01(a)

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

14. Applicant's arguments with respect to claims 1-38, and 40-60 have been considered but are moot in view of the new ground(s) of rejection.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Isis A Ghali/
Primary Examiner, Art Unit 1611

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